CONFORMITY ASSESSMENT INFRASTRUCTURE

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Topic Map

- Value of the conformity assessment (CA) infrastructure
- Use of the CA infrastructure in the US
- A walk through the CA infrastructure

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Value of the conformity assessment infrastructure

- Confidence
  - Products conform to requirements (standards)
  - Evidence of conformance (test results)
  - Attestation of conformance (supplier or certifier)
  - Attestation of competence of tester or certifier (accreditation)
- Current and ongoing
- Evidence and attestations can be leveraged for different markets and economies

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Use of the CA infrastructure in the US

- US industry has a rich history of developing conformity assessment programs to meet society's needs
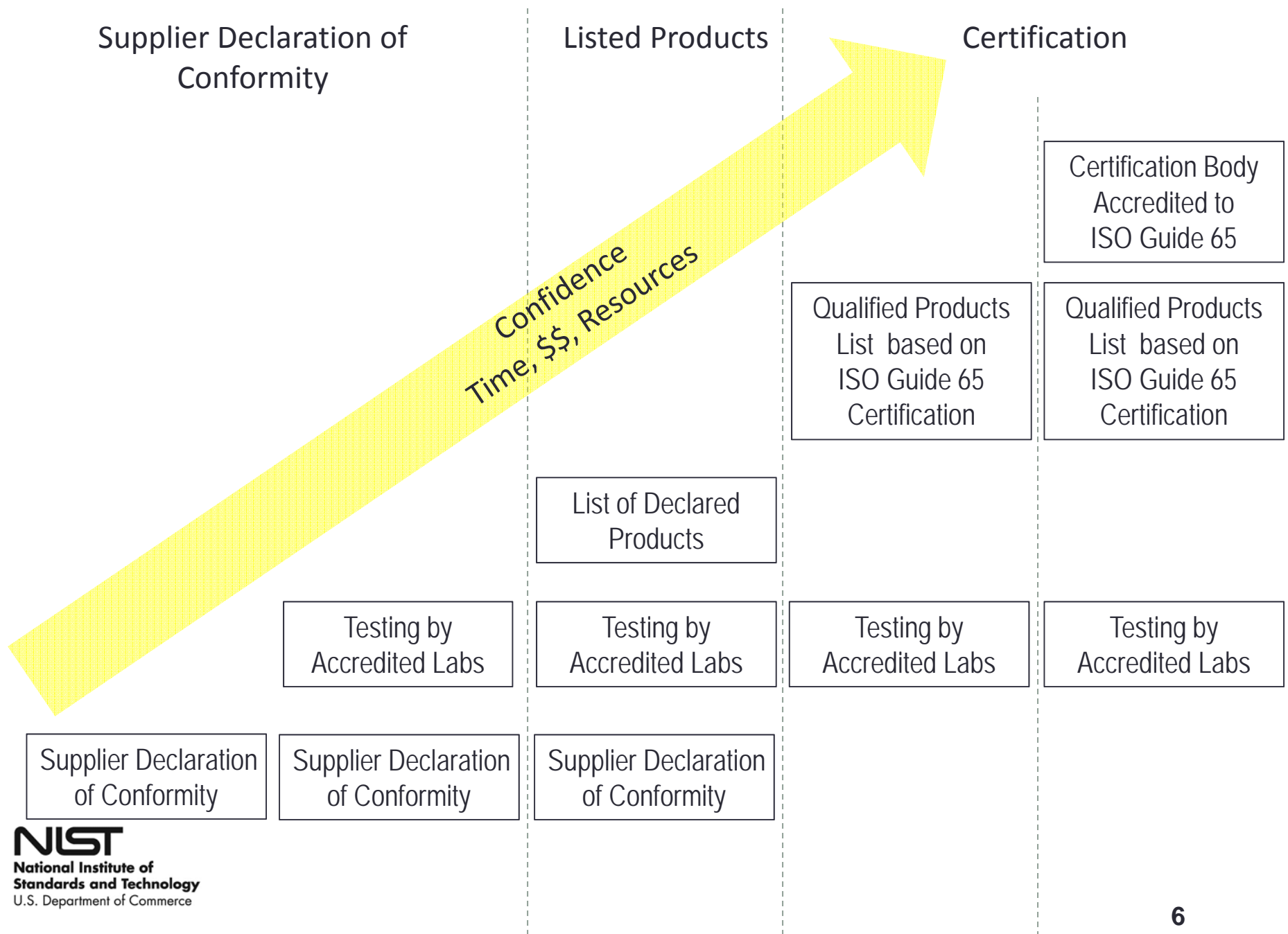 - safety, quality, interoperability, security, and more

- US agencies use the CA infrastructure to meet conformity requirements for regulatory and voluntary programs
  - NTTAA for voluntary standards consideration
  - OMB A119 for CA (NIST to help reduce duplication burden)
  - NIST emphasized risk-based approach; emphasis on using CA infrastructure
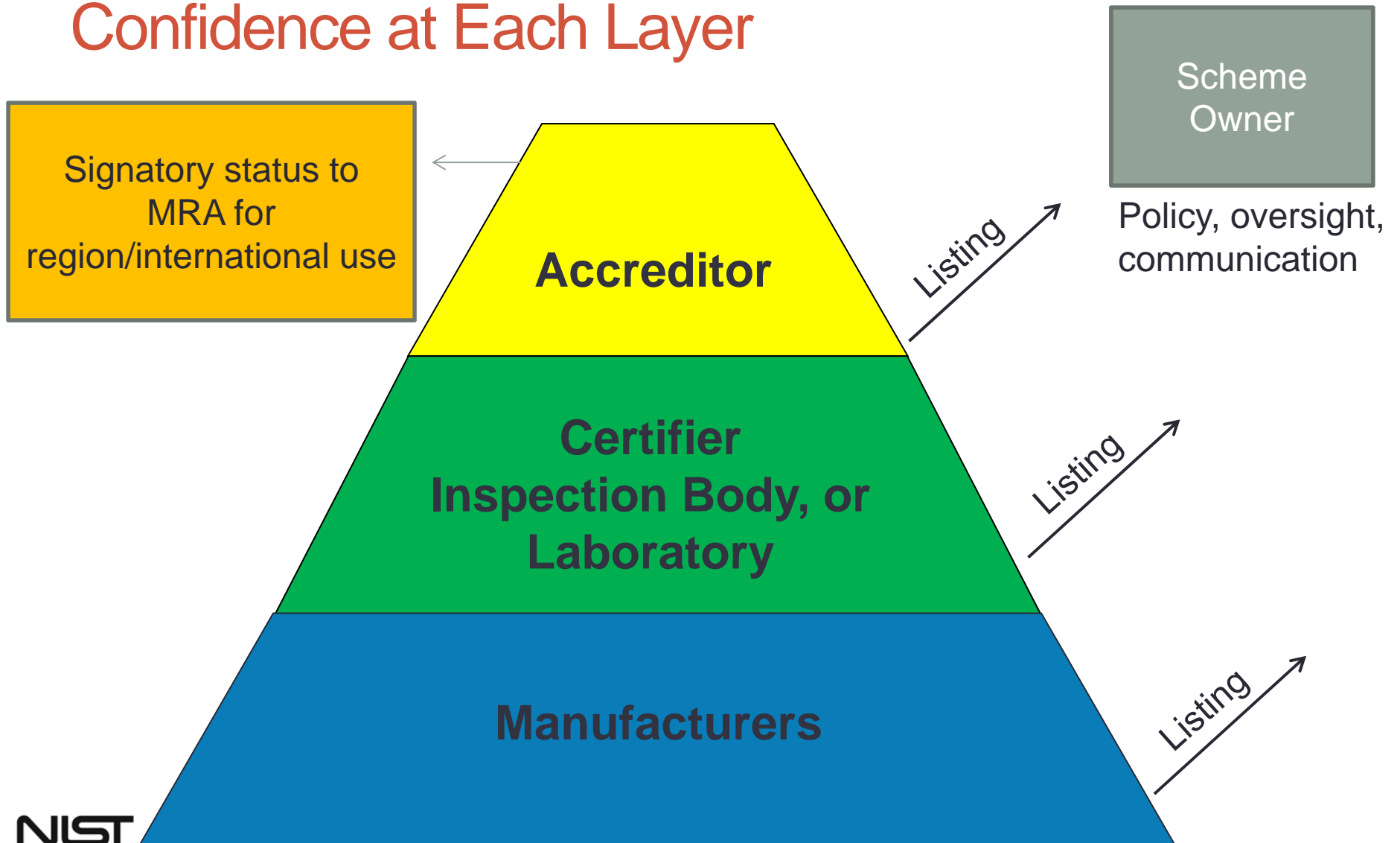 - CPSC (toys), HHS (health records), EPA (WaterSense), NIST (crypto)

A Walk Through the CA Infrastructure

- The US has a healthy market for conformity assessment bodies
  - Testing labs
  - Inspection bodies
  - Audit bodies
  - Certification bodies
  - Accreditation bodies
  - Organizations issuing SDOCs – numerous in many markets

  - Surveillance activities

  - Leveraging results for use in other markets & economies
    - Test results, inspection results, attestation, accreditation
    - Lessens burden on supplier and conformity assessment body

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Relationship of CA Types and Confidence

Supplier Declaration of Conformity	Listed Products		Certification
			Certification Body Accredited to ISO Guide 65
		Qualified Products List based on ISO Guide 65 Certification	Qualified Products List based on ISO Guide 65 Certification
	List of Declared Products		
Testing by Accredited Labs	Testing by Accredited Labs	Testing by Accredited Labs	Testing by Accredited Labs
Supplier Declaration of Conformity	Supplier Declaration of Conformity	Supplier Declaration of Conformity	

Confidence Time, $$, Resources

Confidence at Each Layer

Conformity Assessment - ISO Guides and Standards

Testing and Calibration Laboratories	Product Certification Bodies	Management Systems Registrars - Quality and Environment	Inspection Bodies
Mutual Recognition Arrangement (ILAC, APLAC, EA, IAAC)	Multilateral Recognition Arrangement (IAF)	Multilateral Recognition Arrangement (IAF)	Mutual Recognition Arrangement (ILAC and IAF, APLAC, EA, IAAC)
Accreditation Bodies (ISO/IEC 17011)	Accreditation Bodies (ISO/IEC 17011)	Accreditation Bodies (ISO/IEC 17011)	Accreditation Bodies (ISO/IEC 17011)
Accredited testing and calibration laboratories (ISO 17025)	Product certification Bodies (ISO/IEC 17065)	Registrars (ISO/IEC 17021)	Inspection Bodies (ISO 17020)
Samples (Test methods and sampling methods)	Products and services (Appropriate product or service standards)	Companies or organizations (ISO 9000, ISO 14000, or equivalent)	Products (Appropriate product standards)

The CA Infrastructure